

REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, are respectfully requested in light of the remarks which follow.

Applicants would like to thank the Examiner for the interview with Applicants' representative on July 24, 2007, regarding the present invention and proposed claim amendments that may place the application in condition for allowance. Further to the interview, and in order to clarify the inventive subject matter, Applicants submit the foregoing amendments to the claims.

In particular, claim 58 has been amended to include the full names of the trophic factors and cytokines recited in part (i) of step (a); to recite an initial concentration of "from 8 to 12%" rather than "12-8%" in part (iii) of step (a); and to recite "a lower concentration of" rather than "less of" in step (b). These and other editorial amendments to the claims have been made to clarify the claim language and bring the claims into better conformance with U.S. patent practice, and are not intended to change the scope of the claims or any elements recited therein.

In the interview, the Examiner indicated that the foregoing editorial amendments, along with the claim amendments set forth in the prior response (*see* the Amendment and Reply previously filed on May 22, 2007 and submitted in conjunction with the Request for Continued Examination on June 27, 2007) should be sufficient to overcome the outstanding rejections under 35 U.S.C. § 112 (written description and enablement), and should serve to clarify the claim language. Accordingly, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections under 35 U.S.C. § 112.

In addition, claim 58 has been further amended by replacing the phrase "until the medium is free of all of the trophic factors and cytokines" with the phrase "until the medium

is free of *all exogenous* trophic factors and cytokines." This amendment is supported throughout the application as filed, for example at page 10, lines 9-12.

With regard to the 35 U.S.C. § 102 rejection over Pain et al., the Examiner acknowledged in the interview that the reference does not appear to teach a stem cell line that is capable of proliferating in a medium that does not contain exogenous LIF. However, the Examiner indicated that because step (b) of claim 58 only recites removal of the trophic factors and cytokines recited in step (a), and does not require removal of *all* trophic factors and cytokines, the claim encompasses a primary medium that contains LIF. In addition, according to the Examiner, if the medium contains serum, the medium cannot be free of all exogenous trophic factors and cytokines.

The present inventors have surprisingly discovered that it is possible to proliferate chicken embryonic stem cells in the absence of exogenous trophic factors and cytokines, including LIF. Further, as noted above, Applicants have clarified this aspect of the invention by amending the last clause of step (b) of claim 58 to read "until the medium is free of *all exogenous* trophic factors and cytokines" rather than "until the medium is free of all *of the* trophic factors and cytokines." Pain et al. teaches that exogenous LIF is necessary for culturing and proliferating chicken embryonic stem cells. For at least this reason, the reference does not teach or even suggest the methods recited in the present claims.

In response to the Examiner's position regarding serum, Applicants respectfully submit that a medium "free of all exogenous trophic factors and cytokines" is not necessarily serum-free. In particular, the term "exogenous trophic factors and cytokines," as used in the present specification, refers to components that are independently added to the culture medium, and clearly does not include any trophic factors and cytokines that may be components of any fetal calf serum that may be used to supplement the basal medium (see,

e.g., page 12, lines 1-5 and 13-17, presenting medium "free of exogenous [trophic factors and cytokines]" and "serum-free medium" as alternative embodiments of the present invention).

In addition, a person of ordinary skill in the art would immediately recognize that the terms "exogenous trophic factors" and "exogenous cytokines" are used to describe components that are independently added to a culture medium, and do not refer to trophic factors or cytokines that may be components of any added fetal serum. In support of this position, Applicants submit herewith the following references:

Paulsen et al., PNAS 2001 (*see, e.g.*, page 1389, Legend of Figure 2, noting that the cells were cultivated in DMEM medium containing 10% FBS in the presence or absence of "exogenous growth factors" (TGF α , FGF, EGF, etc.) added independently to the culture medium);

Ettenberg et al., Oncogene 1999 (*see, e.g.*, page 1862, Table 1 for exogenous growth factors added, page 1865, column 1 in the paragraph "Cell culture" for the composition of the medium and the paragraph "Discussion" page 1863, column 2, lines 11-12, using the term "exogenous growth factors");

Crocker et al., J. Exp. Med. 1985 (*see, e.g.*, page 1007, paragraph "Fate and stability in culture," describing medium comprising "10% FBS, without exogenous growth factors");

Fayette et al., J. Exp. Med. 1997 (*see, e.g.*, page 1910, 1st column, paragraphs "Generation of D-Lc from CD34+ cells" and "Culture in the CD40L System") describing a culture medium with FCS and page 1912, Legend of Figure 2, indicating that the culture medium is "without exogenous cytokine"); and

Ferlin-Bezombes et al., J. Immunol. 1998 (*see, e.g.*, page 2693, Legend of Figure 1, describing "culture medium supplemented with 10% FCS either without exogenous cytokine or with IL-6...").

In view of the above, Applicants respectfully request reconsideration and withdrawal of the outstanding rejection under 35 U.S.C. § 102.

The amendments to the claims have been made without prejudice or disclaimer to any subject matter recited or canceled herein. Applicants reserve the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new matter has been added, and entry of the foregoing amendments of the above-identified application are respectfully requested.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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By:



Lisa E. Stahl

Registration No. 56,704

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6609